Approved for use through 07/31/2012. OMB 0651-0931

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons required in respond to a collection of information unless it contains a valid OMB control maniter.

	***************************************		••	Complete if Known		
Substitute for form 1449/PTO INFORMATION DISCLOSURE				Application Number	09/990,909	
			LOSURE	Filing Date	November 16, 2001	
STATEMENT BY APPLICANT		First Named Inventor	Joan M. Fallon			
(Use as	(Use as many sheets as necessary)		Art Unit	1645		
		Examiner Name	Virginia Allen Portner			
Sheet	. 1	of	4	Attorney Docket Number	41012-705.201	

Examiner Initials*	Cite No. <sup>5</sup>	Document Sumber Number-Kind Code' (If known)	Publication Date MM-DD-YYYY	Same of Patentae or Applicant of Ched Document	Pages, Columns, Lines, Where Relevant Passages et Relevant Figures Appear
	1.	US 13/002,136	Appin filed 12/30/10	Fallon	
	2.	US 2002/0037284 A1	03/01/2002	Fallon	
*****	3.	US 2002/0090653 A1	07/11/2002	Fallon	
*******	4.	US 2004/0071683 A1	04/15/2004	Fallon	***************************************
	5.	US 2004/0101562 A1	05/27/2004	Maio	
***************************************	6.	US 2004/0121002 A1	06/24/2004	Lee et al.	
*******	7,	US 2006/0182728 A1	08/17/2006	Fallon	
	8.	US 2006/0183180 A1	08/17/2006	Fallon	
***************************************	9,	US 2006/0198838 A1	09/07/2006	Fallon	
	10.	US 2007/0116695 A1	05/24/2007	Failon	
	11.	US 2008/0058282 A1	03/06/2008	Failon	
	12.	US 2008/0152637 A1	06/26/2008	Fallon	
	13.	US 2008/0161265 A1	07/03/2008	Fallon et al.	
***************************************	14.	US 2008/0219966 A1	09/11/2008	Fallon	
***************	15.	US 2008/0279839 A1	11/13/2008	Schuler et al.	
	16.	US 2009/0130081 A1	05/21/2009	Fallon	
	17.	US 2009/0197289 A1	08/06/2009	Fallon	
	18.	US 2009/0232789 A1	09/17/2009	Fallon	
	19,	US 2009/0263372 A1	10/22/2009	Fallon	
	20.	US 2009/0285790 A1	11/19/2009	Fallon	
	21.	US 2009/0286270 A1	11/19/2009	Fallon	
*******	22.	US 2009/0324572 A1	12/31/2009	Fallon	<del>(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</del>
*******	23.	US 2009/0324730 A1	12/31/2009	Fallon	
•	24.	US 2010/0092447 A1	04/15/2010	Fallon	<del>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</del>
	25.	US 2010/0169409 A1	07/01/2010	Fallon et al.	
	26.	US 2010/0233218 A1	09/16/2010	Fallon	
	27.	US 2010/0260857 A1	10/14/2010	Fallon et al.	
	28.	US 3,002,883	10/03/1961	Butt et al.	
Examiner Signature				Date Considered	

<sup>\*\*</sup>EXAMNER: Initial if reference considered, whether or ant citation is in conformance with SCPEP 609. Draw line through citation if not in conformance and cut considered. Include copy of this form with next occurrenced to specificate. Applican's unique citation designation number (options). See Kinth Codes of UNIFTO Extent Documents at www.seggg gay or MPSP 901.04. Extent Office that issued the document, by the two-letter code (WIPO Standard ST.3). On Expanses patient documents, the following of the period the reign of the Emperor tourt precede the serial number of the patient document. Using of document by the appropriate symbols as indicated on the document wider WIPO Standard ST.16 if possible. \*Applicant is to place a

the best of the best of English Imagings Translation is stateded.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is so the fand by the USFTO to process an application. Confidentially is generous by 35 U.S.C. 122 and 37 CFR 1.14. This solication is assumed in take 2 hours in complete, including gathering, preparing, and standing the completed application from the USFTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form such as well as a solid to sent to the City To Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form such a suggestions for adulting this formation, should be sent to the City To Time will be a solid to sent to the City To Time will be a solid to sent to the City To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city To Time will be a solid to the city FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Sox 1450, Alexandria, VA 22313-1458.

If you need assistance in completing the form, cell 1-203-27C 9199 (1-203-786-9199) and select option 2

PTO/SB/08a (07-09)

Approved for use through 07/31/2012. OMB 0651-9031 U.S. Patent and Trademark Office; U.S. DEFARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

				Co	Camplete if Known		
Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	09/990,909				
		Filing Date	November 16, 2001				
		First Named Inventor	Joan M. Fallon				
		Art Unit	1645				
		Examiner Name	Virginia Allen Portner				
Sheet	2	of	4	Attorney Docket Number	41012-705.201		

		U.S. PA	TENT DOC	UMENTS	
Exactimer Initists*	Cite No.	Document Number Number-Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patenties or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	29,	US 5,324,514	06/28/1994	Sipos	
	30.	US 5,437,319	08/01/1995	Garuglieri	
	31.	US 6,011,001	01/04/2000	Navia et al.	
	32.	US 6,743,447	06/01/2004	Labergerie et al.	

		FOREIGN	PATENT DO	OCUMENTS	2	
Examines Initials*		Foreign Pstent Discument	Publication Date MM-DD-YYYY	Name of Patenies or Applicant of Cited Document	Pages; Columns, Lones, Where Relevant Passages	10
***************************************		Country Code" - Westber - Kital Code" (If known)			Or Relevant Figures Appear	
	33.	WO 2002/014537 A2	02/21/2002	Failon		
	34.	WO 2002/014537 A3	05/10/2002	Fallon		
	35.	WO 2009/114757 A2	09/17/2009	Fallon		
	36.	WO 2010/002972 A1	01/07/2010	Fallon		}
	37.	WO 2010/080830 A1	07/15/2010	Fallon et al.		
	38.	WO 2010/080835 A1	07/15/2010	Fallon et al.		

Examiner		Date	
Signature		Considered	
in a contract of the contract	Contract of the contract of th		

<sup>\*</sup>EXAMINED: Initial of inference considered, whether or not citation is in confirmance with MPEP 509. Draw line through clinics if not in confirmance and not considered. Include cupy of this form with next communication in applicant. "Applicant's unique challes distinguisher number (spitions)." See Einds Cortes of USPPO From the amount at agree, again, agree on MPEP.

\$1.50. "Enter Office that insued the decrement, by the two-lesses code (WPO Standard ST.1)." For laptacine patent document, the indication of the year of the reign of the Emperor must precede the social number of the patent document, "Kind of incomment by the appropriate spintolis is indicated on the document water WPO Standard ST.16 if possible." Applicant is to place a check mark here if English tenguage Translation is establed.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or ratain a bounds by the public which is to the fame by the DSFTO to process) an application. Confidentially is governed by 38 U.S.C. 122 and 37 CFR 1.14. This confection is estimated to take 2 forces to complete, including galaxing, magazing, and authoriting the completed implication form to the CSFTO. Time will vary depending upon the individual cases. Any comments on the amount of tone you require to complete this form analysis suggestions for reducing this binden, should be seen to the Chief Information Cifficer, U.S. Passes and Trademark Ciffice, P.O., See, 1450, Alexandria, VA 22313-1450, TO NOT SEED PRES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Parsons, P.O. Ben 1486, Alexandria, VA 22313-1450.

If you need activitizes in completing the form, cell 1-809-FTO-9199 (1-800-786-9199) and telest option 2.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Parerwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

		***************************************	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Complete if Known		
Substitute	Substitute for form 1449/PTO INFORMATION DISCLOSURE		Application Number	09/990,909		
TNFOR			Filing Date	November 16, 2001		
STATEMENT BY APPLICANT (Use as many sheets as necessary)		First Named Inventor	Josn M. Fallen			
		Art Unit	1645			
		Examiner Name	Virginia Allen Portner			
Sheet	3	of	4	Attorney Docket Number	41012-705.201	

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	L <sub>3</sub>
	39.	BRUDNAK et al. Enzyme-based therapy for autism spectrum disorders — is it worth another look?  Med Hypoth, 2002; 58:422-428.	
	40.	Final Office Action dated 2/14/11 for US Application 12/049,613.	
	41.	HENDREN et al. Mechanistic biomarkers for autism treatment. Medical Hypotheses. 2009; 73:950-954.	
***************************************	42.	International search report and written opinion dated 1/18/11 for PCT/US2010/057341	
	43.	International search report and written opinion dated 2/15/11 for PCT/US2010/053484	
	44.	International search report and written opinion dated 6/9/10 for PCT/US2010/030895	
	45.	LIEBERMAN. Pharmaceutical Dosage Forms, Vol. 2; Disperse Systems, New York Marcel Dekker, Inc. 1996; 243-258.	
***************************************	46.	LIPASE 30, Technical Data sheet, 1 page, Scientific Protein Laboratories LLC 6/13/05	
	47.	Office Action dated 1/21/11 for US Application 12/386,051.	
	48.	Office Action dated 10/1/01 for US Application 09/466,559.	
•••••••••••	49,	Office Action dated 10/5/10 for US Application 12/046,402.	
***************************************	50.	Office Action dated 11/15/10 for US Application 12/238,415.	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	51.	Office Action dated 4/22/03 for US Application 09/929,592.	
	52.	Office Action dated 7/22/10 for US Application 12/049,613.	
**************	53.	Office Action dated 8/13/02 for US Application 09/929,592.	
	54.	Office Action dated 8/20/10 for US Application 12/283,090.	
	55.	Office Action dated 8/25/10 for US Application 12/487,868.	-

	<u>,</u> ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	 eganimien,	Accesses	•••
Examiner			Date		1
Signature			Considered	<b>§</b>	3

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not clustion is to confirmance with MPEP 659. Draw line through clusters if not in confirmance and not considered. Include copy

of this firsts with next communication to applicant.

\*Applicant is unique citation designation number (optional): \*Applicant is to place a checkmark here if finglish inequage Yearsleifou is searched.

This policition of information is required by 37 (278-1.98. The information is required to obtain or retain a henceful by the public which is to file (and by the USPYO to process) on application. Confidentially is governed by 33 U.S.C. 122 and 37 CFR [1.4]. This collections is stepsized to take 2 hours to complete, including gathering, propering, and submitting the completed application form to the USFTO. Thus will vary depending upon the individual case. Any comments on the amount of time you require to complete from the first burden, should be sent to the Chief Information Office, U.S. Peem and Prademark Office, F.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND PEES OR COMPLETED FORMS TO THIS AUBBRISE. SEND TO: Commissioner for Patients, F.O. Box 1459, Alexandria, VA 22313-1450. DO NOT SEND PEES OR COMPLETED FORMS TO THIS AUBBRISE. SEND TO: Commissioner for Patients, F.O. Box 1459, Alexandria, VA 22313-1450.

If you need arrivance in completing the form, call I-800-PTC-9199 [I-800-786-9199] and select option 3.

YTO/SB/08b (07-09)

Approved for use through 07/31/2012, OMB 9651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

•			*:	Con	Complete if Known		
Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	09/990,909				
		Filing Date	November 16, 2001				
		First Named Inventor	Joan M. Fallon				
		Art Unit	1645				
		Examiner Name	Virginia Allen Portner				
Sheet	4	of	4	Attorney Docket Number	41012-705.201		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	75
	56.	Pancreatic Enzyme Concentrate (PEC) Undiluted, Technical Data Sheet. 1 page, Scientific Protein Laboratories LLC 6/13/05	
	57.	Pancreatin 4X USP, Technical Data Sheet, 1 page, Scientific Protein laboratories LLC 6/13/05	
	58.	SCHRECK et al. Food preferences and factors influecing food selectivity for children with autism spectrum disorders. Res Develop Disabil. 2006; 27:353-363.	
	59.	STEIN, et a. Nitrogen Metabolism in normal and hyperkinetic boys. Am J Clin Nutr. 1984; 39:520-524.	
	60.	USP (32)-NF(27) 2009, Pancreatin, V.3, pp.3194-3195.	
	61.	WENDER et al. Prevalence of attention deficit disorder, residual type, and other psychiatric disorders in patients with irritable colon syndrome. Am J Psychiatry. 1983; 140(12):1579-82 Abstract only.	

***************************************				٠.
Examiner	/Albert M Navarro/	Date	NS/40/2011	
Signature		Considered	00/10/2011	ŀ

<sup>\*</sup>EXAMINES. total if reference considered, whether or an estation is in conference with MPEP 809. Draw fine through estation if not is combinations and not considered. Include capty

<sup>\*</sup>EXAMINES. total if reference possidence, whether or and electron is in conformance with MPEP 809. One true carroing custom is not communication to options.

Applicant is unique classical and successful and the place of shockmark here if English language Translation is stateched.

This collection of information is required by 37 CFR 1,98. The information is required to obtain or region a benefit by the public which is to file (and by the USPTO to process) as application. Considerationly is governed by 33 U.S.C. 122 and 31 CFR 1,98. The information is required to take 2 hours as complete, including gathering, preparing, and setemating the completed application from to the USPTO. There will have depending upon the information of the paint of these paint requires to complete this intensities registrates for reducing this bodies, should be sent to the Chief Information Officer, U.S. Pasent and Trademark Officer, P.O. Star 1480, Alexandria, VA 23315-1450. DO NOT STAID FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Son 1450, Alexandria, VA 23313-1450.

If you need estimate in completing the form, cell 1-509-PTO 9/19/1-809-786-9/190) and select option 2.